



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re PATENT APPLICATION of

Yoshikatsu KODAMA et al.

Atty. Docket No.: 2004\_2037A

Serial No. 10/519,536

Art Unit: 1645

Filed: December 28, 2004

Examiner: Lynetter. F. Smith

For: ANTI-CHICKEN COCCIDIOSIS COMPOSITION

DECLARATION PURSUANT TO 37 C.F.R.1.132

1. I, Yoshikatsu KODAMA, do hereby declare as follows:

I had Ph.D. from University of Tokyo in 1978. Since April, 1978, I have been employed by GHEN Corporation. I have a full knowledge of the present invention and cited references.

2. In order to demonstrate the patentability of the present invention, the following experiment was carried out.

The animal used in this evaluation was "Cobb" which is a chicken breed. A broiler feed comprising Chick Start™ in an amount of 500 g / 1t was administered to baby chicks until the chicks became 18 days old. Then a broiler feed comprising Chick Start™ in an amount of 250 g / 1t was administered to the chicks until shipping. Chick Start™ is a product of GHEN Corporation which comprises  $6.4 \times 10^7 \sim 1.3 \times 10^8$  / 1kg (ELISA Titer) of the anti-chicken coccidiosis antibody of the present invention. As a positive control, a broiler feed comprising Salinomycin in an amount of 100g / 1t was administered to baby chicks until shipping. Salinomycin has been widely used as an anti- coccidiosis agent. The result is shown in Table 1.

Table 1

Agent administered	Farm	Chicks receipt	Chicks shipped	Rate of maturity (%)	Average weight (g)	Feed conversion rate
Antibody of the invention	A	5100	4879	95.7	2.363	1.929
	B	5400	5110	94.6	2.474	1.929
	C	5900	5782	98	2.511	1.972
Salinomycin (positive control)	A	6750	6427	95.2	2.276	2.188
	B	6300	5971	94.8	2.149	2.188
	C	5550	5269	94.9	2.52	1.986

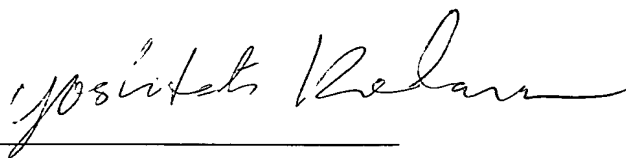
The farms were contaminated with Eimeria species. Therefore, Chicks would be infected with Eimeria species and would be affected with coccidiosis without agents such as Salinomycin. When Chicks are affected with coccidiosis, average weight and rate of maturity will greatly decrease, as a result, productivity will greatly decrease.

It is demonstrated that the antibody of the present invention has an equivalent preventive activity against coccidiosis as compared to Salinomycin. Salinomycin is known to have a good preventive activity against coccidiosis. Therefore, it is demonstrated that the antibody of the present invention can protect the uninfected chicks from coccidiosis.

Although Salinomycin is effective as an anti-coccidiosis agent, it is considered to be toxic to human. In contrast, since the antibody of the present invention is a natural product, it is equally effective as an anti-coccidiosis agent but harmless to human.

3. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: This 5<sup>th</sup> day of June, 2006

A handwritten signature in black ink, appearing to read 'Yoshikatsu Kodama', is written over a horizontal line.

Yoshikatsu KODAMA